IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LABORATOIRE HRA PHARMA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Laboratoire HRA Pharma ("HRA" or "Plaintiff"), by its attorneys, files this Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant") and alleges as follows:

NATURE OF THE ACTION

1. This action is for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 207952 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell Ulipristal Acetate Oral Tablets, 30 mg, a generic version of HRA's ella® drug product, prior to expiration of U.S. Patent Nos. 8,426,392 (the "'392 patent"); 8,512,745 (the "'745 patent"); and 8,735,380 (the "'380 patent") (collectively, the "patents-in-suit").

THE PARTIES

2. Plaintiff HRA is a French corporation having a principal place of business at 15, rue Béranger, 75 003 Paris, France.

3. HRA is engaged in the business of creating, developing, and bringing to market innovative biopharmaceutical products and treatments to help patients in the area of women's

reproductive health and endocrinology. HRA markets and sells ella® in this judicial district and throughout the United States

4. Upon information and belief, Defendant Teva is a Delaware corporation, having a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

JURISDICTION AND VENUE

5. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the patents-in-suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Teva because, upon information and belief, Teva is a Delaware corporation.

7. This Court also has personal jurisdiction over Teva because, *inter alia*, this action arises from actions of Teva directed toward Delaware, and Teva has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Teva regularly and continuously transacts business within the State of Delaware, including by selling and distributing pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Teva derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

8. Teva has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims and by filing suits in Delaware.

9. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

11. Plaintiff HRA is the lawful owner of the '392 patent. On April 23, 2013, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '392 patent, entitled "Method for Providing Emergency Contraception," and naming Erin Gainer and Henri Camille Mathe as inventors. The expiration date for the '392 patent, as listed in the Orange Book, is June 12, 2030. A true and correct copy of the '392 patent is attached as Exhibit A.

12. Plaintiff HRA is the lawful owner of the '745 patent. On August 20, 2013, the USPTO duly and lawfully issued the '745 patent, entitled "Ulipristal Acetate Tablets," and naming Erin Gainer, Hélène Guillard, Denis Gicquel, Marianne Henrion, and Céline Gnakamene as inventors. The expiration date for the '745 patent, as listed in the Orange Book, is February 14, 2030. A true and correct copy of the '745 patent is attached as Exhibit B.

13. Plaintiff HRA is the lawful owner of the '380 patent. On May 27, 2014, the USPTO duly and lawfully issued the '380 patent, entitled "Ulipristal Acetate Tablets," and naming Erin Gainer, Hélène Guillard, Denis Gicquel, Marianne Henrion, and Celine Gnakamene as inventors. The expiration date for the '380 patent, as listed in the Orange Book, is February 20, 2029. A true and correct copy of the '380 patent is attached as Exhibit C.

PLAINTIFF HRA'S APPROVED ELLA® DRUG PRODUCT

14. Plaintiff HRA makes and sells ella® (ulipristal acetate), a prescription medicine that provides emergency contraception to prevent pregnancy within five days after unprotected intercourse or a known or suspected contraceptive failure. Ella® is indicated for administration orally with or without food. Ella® is not indicated for termination of an existing pregnancy, or for routine use as a contraceptive.

15. Ella® is a selective progesterone receptor modulator with antagonistic and partial agonistic effects (a progesterone agonist/antagonist) at the progesterone receptor. It binds the

human progesterone receptor and prevents progesterone from occupying its receptor. When taken immediately before ovulation is to occur, ella® postpones follicular rupture.

16. Plaintiff HRA is the holder of New Drug Application ("NDA") No. 022474 for ella® (30 mg).

17. The FDA approved NDA No. 022474 on August 13, 2010, for the manufacture, marketing, and sale of ella® as a progesterone agonist/antagonist emergency contraceptive indicated for prevention of pregnancy within five days after unprotected intercourse or a known or suspected contraceptive failure. The FDA has not approved ella® for use during a known or suspected pregnancy, or for routine use as a contraceptive. Plaintiff HRA has sold ella® under NDA No. 022474 since its approval.

18. The new chemical entity exclusivity for ella® expires on August 13, 2015.

19. The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering ella®.

THE DRUG APPROVAL PROCESS

20. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act," and codified at 21 U.S.C. § 355. The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that innovator drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

21. Under 21 U.S.C. § 355(b)(1), the innovative drug manufacturer and NDA applicant is required to submit extensive testing and safety information concerning the drug. In

addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

22. In contrast, the Hatch-Waxman Act allows ANDA applicants to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. Under 21 U.S.C. § 355(j), ANDAs can rely on the FDA's previous findings of safety and efficacy for an approved drug product, if they demonstrate, among other things, that the generic drug is bioequivalent to the previously-approved drug.

23. When a generic manufacturer submits an ANDA, the FDA conducts a preliminary review of the application to ensure it is sufficiently complete to permit a substantive review. *See* 21 C.F.R. § 314.101(b)(1). "Receipt of an [ANDA] means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review." *Id.*

24. Under 21 U.S.C. § 355(j)(2)(A)(vii), the ANDA must also include one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed ("Paragraph I" certifications); (ii) that the patent has expired ("Paragraph II" certifications); (iii) that the patent will expire on a specific date ("Paragraph III" certifications); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" ("Paragraph IV" certifications).

25. Paragraph IV certifications can allow generic manufacturers to obtain FDA approval long before expiration of the patents listed in the Orange Book

26. If the ANDA includes a Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice ("notice of Paragraph IV certification") to the patent owner of the factual and legal basis for the applicant's opinion that patents listed in the Orange Book are invalid or will not be infringed, "not later than 20 days after the date of the postmark on the notice with which the [FDA] informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B).

27. The patent owner can file an infringement action within 45 days of receiving the notice of Paragraph IV certification. Such a filing by the patent owner triggers a 30-month injunction or stay of the FDA approval, beginning on the date of receipt of the notice. *See* 21 U.S.C. § 355(j)(5)(B)(iii). This 30-month period is intended to allow time for judicial resolution on the merits of any patent infringement, validity, and/or enforceability claims, before the competitor is allowed entry into the market.

28. Federal regulations also govern the timing of the notice of Paragraph IV certification by directing the generic manufacturer to send such notice "when it receives from FDA an acknowledgment letter stating that its [ANDA] is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

DEFENDANT'S ANDA

29. On information and belief, on or before December 5, 2014, Defendant submitted or caused to be submitted to the FDA ANDA No. 207952 ("Teva's ANDA") and a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the commercial manufacture, use, or sale of Ulipristal Acetate Oral Tablets, 30mg ("ANDA Product"), as a purported generic version of ella®, prior to the expiration of the patents-in-suit.

30. On information and belief, on December 5, 2014, Teva sent Plaintiff HRA a "Notice of ANDA No. 207952 Concerning Ulipristal Acetate Oral Tablets, 30 mg With Paragraph IV Certification Concerning U.S. Patent Nos. 8,426,392, 8,512,745 And 8,735,380" ("Notice Letter"). The Notice Letter represented that Teva had submitted to the FDA ANDA No. 207952 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the patents listed in the Orange Book for NDA No. 022474. Hence, Defendant's purpose in submitting the Teva ANDA is to manufacture and market the ANDA Product before the expiration of the patents-in-suit.

31. The Notice Letter also stated that the Paragraph IV certification alleges that the patents-in-suit are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

32. Teva filed its ANDA in the year before the expiration of the five-year new chemical entity exclusivity for ella®. Thus, the 30-month stay provided by 21 U.S.C. § 355(j)(5)(B)(iii) shall be extended by such amount of time (if any) which is required for 7 ½ years to have elapsed from the August 13, 2010 ella® approval date. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

33. Defendant is liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 207952 with a Paragraph IV certification seeking FDA approval of ANDA No. 207952, prior to the expiration of the patents-in-suit.

34. On information and belief, if the FDA approves the Teva ANDA, Defendant will manufacture, offer for sale, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States.

35. The conditions for use of the ANDA Product that is the subject of ANDA No. 207952 fall within one or more claims of the patents-in-suit. If approved, use of Teva's ANDA Product in accordance with the proposed labeling submitted in ANDA No. 207952 would infringe one or more claims of the patents-in-suit.

36. On information and belief, if the FDA approves Teva's ANDA, the importation, manufacture, sale, offer for sale, or use of the ANDA Product that is the subject of ANDA No. 207952 would infringe one or more claims of the patents-in-suit.

37. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiff HRA's receipt of the Notice Letter.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '392 PATENT

38. Plaintiff HRA restates, re-alleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

39. On information and belief, Teva has submitted or caused the submission of ANDA No. 207952 to the FDA, and continues to seek FDA approval of ANDA No. 207952.

40. Teva has infringed the '392 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207952 with a Paragraph IV certification and seeking FDA approval of ANDA No. 207952 prior to the expiration of the '392 patent.

41. If approved, the ANDA Product that is the subject of ANDA No. 207952 will be administered to human patients as a progesterone agonist/antagonist emergency contraceptive for prevention of pregnancy within five days after unprotected intercourse or a known suspected contraceptive failure, which administration with food would constitute direct infringement of one or more claims of the '392 patent. Upon information and belief, this infringement will occur at Defendant's behest, with its intent, knowledge, and encouragement, and Defendant will actively

induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiff HRA's rights under the '392 patent.

42. Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '392 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207952, Teva will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '392 patent.

43. On information and belief, upon FDA approval of ANDA No. 207952, Teva will market and distribute the ANDA Product to resellers, pharmacies, health care professionals, and end users of the ANDA Product. Teva will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using the ANDA Product. Accordingly, Teva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '392 patent. In addition, on information and belief, Teva will encourage acts of direct infringement with knowledge of the '392 patent and knowledge that it is encouraging infringement.

44. Teva had actual and constructive notice of the '392 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '392 patent would constitute an act of infringement of the '392 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale

of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '392 patent. In addition, Teva filed the Teva ANDA without adequate justification for asserting the '392 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Teva's conduct in certifying invalidity and non-infringement with respect to the '392 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

45. Plaintiff HRA will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '392 patent. Plaintiff HRA does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '745 PATENT

46. Plaintiff HRA restates, re-alleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

47. On information and belief, Teva has submitted or caused the submission of ANDA No. 207952 to the FDA, and continues to seek FDA approval of ANDA No. 207952.

48. Teva has infringed the '745 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207952 with a Paragraph IV certification and seeking FDA approval of ANDA No. 207952 prior to the expiration of the '745 patent.

49. Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '745 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207952, Teva will make, use, offer to sell, or sell the

ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the ’745 patent.

50. On information and belief, upon FDA approval of ANDA No. 207952, Teva will market and distribute the ANDA Product to resellers, pharmacies, health care professionals, and end users of the ANDA Product. Teva will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using the ANDA Product. Accordingly, Teva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the ’745 patent. In addition, on information and belief, Teva will encourage acts of direct infringement with knowledge of the ’745 patent and knowledge that it is encouraging infringement.

51. Teva had actual and constructive notice of the ’745 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the ’745 patent would constitute an act of infringement of the ’745 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the ’745 patent. In addition, Teva filed the Teva ANDA without adequate justification for asserting the ’745 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Teva’s conduct in certifying non-infringement with respect to the ’745 patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

52. Plaintiff HRA will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’745 patent. Plaintiff HRA does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III: CLAIM FOR INFRINGEMENT OF THE ’380 PATENT

53. Plaintiff HRA restates, re-alleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

54. On information and belief, Teva has submitted or caused the submission of ANDA No. 207952 to the FDA, and continues to seek FDA approval of ANDA No. 207952.

55. Teva has infringed the ’380 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207952 with a Paragraph IV certification and seeking FDA approval of ANDA No. 207952 prior to the expiration of the ’380 patent.

56. Teva’s commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the ’380 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 207952, Teva will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the ’380 patent.

57. On information and belief, upon FDA approval of ANDA No. 207952, Teva will market and distribute the ANDA Product to resellers, pharmacies, health care professionals, and end users of the ANDA Product. Teva will also knowingly and intentionally accompany the

ANDA Product with a product label and product insert that will include instructions for using the ANDA Product. Accordingly, Teva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '380 patent. In addition, on information and belief, Teva will encourage acts of direct infringement with knowledge of the '380 patent and knowledge that it is encouraging infringement.

58. Teva had actual and constructive notice of the '380 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '380 patent would constitute an act of infringement of the '380 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '380 patent. In addition, Teva filed the Teva ANDA without adequate justification for asserting the '380 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Teva's conduct in certifying non-infringement with respect to the '380 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

59. Plaintiff HRA will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '380 patent. Plaintiff HRA does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff HRA respectfully requests the following relief:

A. A judgment that Defendant has infringed each of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting and maintaining ANDA No. 207952;

B. A judgment declaring that the making, using, selling, offering to sell, or importing of the ANDA Product that is the subject of ANDA No. 207952, or inducing or contributing to such conduct, would constitute infringement of the patents-in-suit by Defendant pursuant to 35 U.S.C. §§ 271 (a), (b), and/or (c);

C. A judgment that the claims of the patents-in-suit are valid and enforceable;

D. Preliminary and permanent injunctions, restraining and enjoining Defendant and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons acting in concert, participation, or in privity with Defendant, and its successors or assigns, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the ANDA Product, or from inducing and/or encouraging infringement of the patents-in-suit;

E. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 207952 is not earlier than the last expiration date of any of the patents-in-suit, including any extensions thereof, and any later expiration of exclusivity associated with those patents;

F. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, and an award of Plaintiff's attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 385;

G. A judgment granting Plaintiff compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendant

commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Defendant's ANDA Product before the expiration of each patent-in-suit that Defendant is found to infringe, including any extensions;

H. An award to Plaintiff of its costs and expenses in this action; and

I. Such other and further relief as the Court deems just and proper.

Dated: January 16, 2015

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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